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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/081,185 | 02/25/2002 | Thomas Dag Horn | 023533-0144 | 4869 |

7590 02/02/2005

HUGH MCTAVISH
MCTAVISH PATENT FIRM
429 BIRCHWOOD COURTS
BIRCHWOOD, MN 55110

| EXAMINER | |
|---|---|
| NICKOL, GARY B | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | |

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/081,185 | HORN ET AL. | |
| | Examiner | Art Unit | |
| | Gary B. Nickol Ph.D. | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *19 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1,4-7,9-12,15-17,33,36,37,40,41,46 and 47* is/are pending in the application.

4a) Of the above claim(s) *9-12,16,17,40,41,46 and 47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-7,15,33,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Re: Horn *et al.*

Date of priority: 06/25/1999

***Response to Amendment***

The Amendment filed 11-19-04 in response to the Office Action of 07-26-04 is acknowledged and has been entered.

Claims 2-3, 8, 13-14, 18-32, 34-35, 38-39, 42-45 were cancelled.

Claims 9-12, 16-17, 40-41, 46-47 have been withdrawn from further consideration by the examiner under 37 CFR 1.142(b) as being drawn to non-elected inventions.

Claims 1, 4-7, 15, 33, 36-37 are currently under consideration.

**The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.**

***Election/Restrictions***

Newly submitted/amended claim 9 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly amended claim 9 does not read on applicant's elected invention, drawn solely to bacterial and candida antigens. See restriction mailed 04/09/2004, page 4, Group II.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution

on the merits. Accordingly, claim 9 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

**Rejections Maintained:**

Claims 1, 4-7, 33, and 36-37 remain rejected under 35 U.S.C. 102(e) as being anticipated by Clements, J. (US Patent No. 6,033,673, March 18, 1998) for the reasons of record and for the reasons set forth below.

Applicants argue (Response, page 8) that the prior art does not disclose that the LT enterotoxin "on its own" induces or is capable of inducing any cell-mediated response, or specifically a cutaneous delayed type hypersensitivity response. Applicants further note that Clements does not even disclose that LT is an antigen itself. Thus, applicants appear to be differentiating potential functional characteristics of each claimed antigen(s) in the pharmaceutical composition versus those antigens present in the pharmaceutical composition taught by Clements.

These arguments have been carefully considered but are not found persuasive. As set forth previously, the claims are drawn to the pharmaceutical composition, *per se*. As such, each of the antigens disclosed by Clements inherently induces or is capable of inducing a cutaneous delayed type hypersensitivity response. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed

practice of the Bostwick reference to either a constructive reduction to practice or an actual reduction to practice. The affidavit does not contain facts showing a completion of the invention that is commensurate with the extent of the invention claimed. The 37 CFR 1.131 affidavit or declaration must establish possession of either the whole invention claimed or something falling within the claim (such as a species of a claimed genus), in the sense that the claim as a whole reads on it. In re Tanczyn, 347 F.2d 830, 146 USPQ 298 (CCPA 1965). Hence, the declaration filed on 11-19-04 under 37 CFR 1.131 has been considered but is ineffective to overcome the Bostwick reference.

Claims 1, 4-7, 33, and 36-37 remain rejected under 35 U.S.C. 102(e) as being anticipated by Clements, J. (US Patent No. 6,033,673, March 18, 1998) for the reasons of record and for the reasons set forth below.

Applicants argue (Response, page 8) that the prior art does not disclose that the LT enterotoxin "on its own" induces or is capable of inducing any cell-mediated response, or specifically a cutaneous delayed type hypersensitivity response. Applicants further note that Clements does not even disclose that LT is an antigen itself. Thus, applicants appear to be differentiating potential functional characteristics of each claimed antigen(s) in the pharmaceutical composition versus those antigens present in the pharmaceutical composition taught by Clements.

These arguments have been carefully considered but are not found persuasive. As set forth previously, the claims are drawn to the pharmaceutical composition, *per se*. As such, each

of the antigens disclosed by Clements inherently induces or is capable of inducing a cutaneous delayed type hypersensitivity response. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). Further, it is noted that that the claims do not specifically recite nor require that the LT antigen, "on its own" induce or be capable of inducing a DTH. The claims only require that both antigens be present together as a pharmaceutical composition and that each antigen be capable of inducing a DTH. In other words, there is no recitation that each antigen on its own, free of a pharmaceutical composition, induce or be capable of inducing a DTH reaction. Applicants are reminded that arguments that rely on particular distinguishing features are not persuasive when those features are not recited in the claims. Thus, applicants arguments have not been found persuasive and the rejection is maintained.

Additionally, claims 1, 4-7, 15, 33, and 36-37 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Clements, J. (US Patent No. 6,033,673, March 18, 1998) or Bostwick, E. (US2002/0009429 A1, January 29, 1999) in further view of the CANDIN® package insert text, IDS, Reference A12, submitted March 14, 2003.

Applicant's arguments (Response, page 11) are substantially similar to those set forth above with regards to the teachings of Clements and are not found persuasive for the reasons of record. Thus, the rejection is maintained.

**All other rejections and or objections are withdrawn in view of applicant's amendments and arguments there to.**

No claim is allowed.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.
Primary Examiner
Art Unit 1642

GBN

Gary B Nickol

GARY NICKOL
PRIMARY EXAMINER